REMARKS

The foregoing amendment and remarks which follow are responsive to the final Office Action mailed March 24, 2003 in relation to the above-identified patent application. In that Office Action the Examiner maintained her rejection of Claims 5 and 19 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling with respect to the use of a peptide antigen selected from the group consisting SEQ. ID. NO.: 3-6, (1-34) PTH and (1-84) PTH, allegedly did not reasonably provide enablement for a method utilizing at least one peptide antigen that "comprises" a formula selected from the group consisting of SEQ. ID NOS. 3-6. In this regard, the Office Action repeatedly alleges, albeit incorrectly, that the claims still include the term "comprises" and thus are still believed to be open-ended. See, e.g., Office Action, Sections 5, 6, 8, and 11 ("...there is inadequate written description about the structure of any first peptide antigen "comprises" a formula selected from the group consisting of SEQ. ID NO. 3 ... because the term "comprises" is open ended ...").

For this same reason, namely, the assumption that the claims still are directed to peptide antigens that "comprise" ID SEQ. NOS. 3-6, (1-34 PTH), and (1-84 PTH), , Claims 5, 7, 9, 15, 16, 19 and 24 were rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent Number 4,341,755. Claims 5 and 8-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the same reference (i.e., United States Patent Number 4,341,755) based upon the erroneous assumption that the claims include the term "comprising." Still further Claims 5 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent Number 4,341,755 in view of Heinrich et al., which again relies upon an interpretation that the claims are

directed to protein antigens extending beyond SEQ. ID NOS 3-6, (1-34) PTH and (1-84) PTH.

In addition to the foregoing, the Examiner objected to Claim 24 insofar as the same was directed to "test kits" as opposed to "a test kit," and that Claims 5, 7-10, 15-17, 19 and 24 were rejected under 35 U.S.C. § 112, first paragraph, based upon the previous amendment made to the preamble indicating that such methods were drawn to a method for producing an antibody "having minimal reactivity to PTH-7-84" as appearing in Claim 5.

By this amendment, Applicants have cancelled Claim 19 and has amended Claim 5, from which the remaining claims depend, to delete a portion of the preamble, namely, "having minimal reactivity to PTH 7-84" giving rise to the rejection under 35 U.S.C. § 112, first paragraph. Accordingly, such issues are believed to be moot.

With respect to Claim 5, and consequently the remaining claims depending therefrom, the Examiner is advised that in Applicants' previous amendment submitted in December 2002, Claim 5 was expressly amended to **delete any reference to the term "comprising" and/or "comprises"**. (Applicant's amendment of December 19, 2002, pages 4 and 7-8; Claim 5). Accordingly, and contrary to the statements made in the most recent Office Action, the claims of the present application are directed exclusively to peptide antigens **selected from the group consisting of SEQ. ID NO. 3-6, (1-34) PTH and (1-84) PTH.** The claims are not open-ended with respect to such protein antigens and it will be appreciated that the same are limited to six (6) very discrete and limited amino acid sequences and do not encompass "any" peptide antigens.

In light of such clarification, the grounds for rejecting the claims have clearly been overcome. Indeed, the Office Action expressly states that the present application is enabling with respect to the use of peptide antigens selected from the group consisting of SEQ. ID NO. 3-6, (1-34) PTH and (1-84) PTH. See, Office Action, Section 5. Likewise, because Applicants' methods are limited exclusively to the use of such discreet proteins, such methods are in no way anticipated by or rendered obvious in view of United States Patent Number 4,341, 755, the primary reference relied upon. In this regard, and as had been previously emphasized, such reference fails to teach or disclose the present invention insofar as the same is directed to **antibodies having a high affinity for the C-terminal PTH fragments**. Column 7, lines 21-26. More specifically, United States Patent Number 4,341,755 is directed to **antibodies having a specificity for amino acid residues 65-84 of PTH**. Column 4, lines 6-27; Column 7, lines 19-31; Column 15, lines 39-45; and Abstract. As will be readily appreciated, the antibodies disclosed in United States Patent Number 4,341,755 are not directed against the N-terminal amino acids of PTH, and much less the specific sequences of amino acids as presently claimed.

Based on the foregoing, Applicant respectfully submits that the claims are now clearly in condition for allowance. Early notice to that effect is respectfully requested. To the extent the Examiner has any questions, requires additional information, or has any suggestions to resolve any outstanding issues that may exist, the Examiner is invited to contact Applicants' counsel at the number listed below.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with

markings to show changes made". If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: _____ By: _____

Customer No.: 007663

Matthew A. Newboles
Registration No. 36,224
STETINA BRUNDA GARRED & BRUCKER
75 Enterprise, Suite 250
Aliso Viejo, California 92656
Telephone: (949) 855-1246

## VERSION WITH MARKINGS TO SHOW CHANGES MADE*

IN THE CLAIMS:

Claim 19 has been cancelled without prejudice.

Claims 5 and 24 have been amended as follows:

5. (Thrice Amended) A method for producing an antibody to the N-terminal portion of (1-84) PTH useful in the determination of intact PTH 1-84 levels in a biological sample ~~and having minimal reactivity to PTH 7-84~~, the method comprising the steps:

a) administering a first peptide antigen to a host animal to induce antibody production against said first peptide antigen in said host animal, said first peptide antigen being selected from the group consisting of SEQ ID NO. 3, SEQ ID NO. 4, SEQ ID NO. 5, SEQ ID NO. 6, (1-34) PTH and (1-84) PTH;

b) monitoring antibody titer produced by said administration of said at least one antigen to said host animal;

c) extracting antisera produced in said host animal by said administration of said at least one peptide antigen; and

d) isolating and selecting at least one antibody from said antisera extracted in step c) by affinity chromatography utilizing a second peptide antigen selected from the group consisting of SEQ ID NO. 3, SEQ ID NO. 4, SEQ ID NO. 5, and SEQ ID NO.

24. (Twice Amended) ~~Test kits~~ A test kit and analytical procedures used for the determination of bioactive intact PTH utilizing the antibody produced by the method of Claim 5.

T:\Client Documents\IMUNE\001A\AMENDMENT 061703.doc